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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **WEAVER et al.**

Confirmation No.: **6518**

Serial No.: **10/665,431**

Art Unit: **3733**

Filed: **September 22, 2003**

Examiner: **James L. Swiger III**

For: **BONE PLATING SYSTEM**

Attorney Docket No.: **8932-807-999**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. § 1.56 and MPEP § 2001.06(c), applicants hereby provide further information regarding the existence of a litigation associated with the subject U.S. patent application. Said litigation was previously identified in an Information Disclosure Statement filed on March 5, 2007. The subject application and United States Patent No. 7,128,744 ("the '744 patent") are both continuation applications of U.S. Patent Application Serial No. 09/660,287, which issued as U.S. Patent No. 6,623,486 ("the '486 patent"). Both the '486 patent and the '744 patent have recently been asserted in a patent infringement litigation captioned *Synthes (U.S.A.) v. Smith & Nephew, Inc.*, Civil Action No. 03-0084, pending in the U.S. District Court for the Eastern District of Pennsylvania.

Applicants note that this Information Disclosure Statement includes recently-filed pleadings alleging that inequitable conduct was committed during prosecution of the '486 and '744 patents. Those pleadings and the references allegedly forming the basis for the inequitable conduct allegations are submitted herewith. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

☒ Each publication or that portion which caused it to be listed on the PTO-1449;

☐ For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion that have been checked to be unavailable at the USPTO's private PAIR system;

☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report;

☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications;

- ☐ All other information or portion which caused it to be listed on the PTO-1449.
- 1c. ☐ Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and U.S. patent application publications are not submitted herewith unless required by the office.
- 1d. ☐ Pursuant to 1287 OG 163, copies of cited pending unpublished applications that are available at the USPTO's private PAIR system are not submitted herewith.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☐ Before the mailing of the first Office action on the merits;
- ☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked):

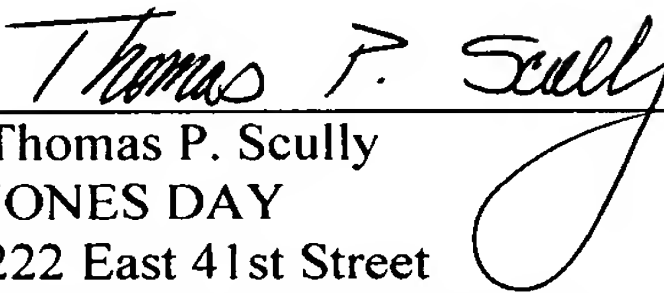
(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☒ This application is a continuation application under 37 C.F.R. §1.53(b) or (d).
(Check appropriate Items 6a, 6b and/or 6c)
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. _____, filed on _____, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☒ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. 09/660,287, filed on September 12, 2000, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on _____. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on _____.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
(Check Item 8a, 8b, or 8c)
- 8a. ☐ Satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ Set forth in the application.
- 8c. ☐ Enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: August 30, 2007


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LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

8932-807-999

APPLICATION NO.

10/665,431

APPLICANT

WEAVER et al.

FILING DATE

September 22, 2003

ART UNIT

3733

U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A01	5,976,141	11/02/99	Haag et al.	
	A02	6,575,975	06/10/03	Brace et al.	
	A03				
	A04				

FOREIGN PATENT DOCUMENTS

*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
	B01	WO 96/25892	08/29/96	Synthes (USA)		
	B02					
	B03					
	B04					

NON PATENT LITERATURE DOCUMENTS

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C01	Defendant's Motion For Leave to Amend Answer To Assert Allegations Of Inequitable Conduct, Civil Action No. 03-0084 (E.D. Pa.), dated August 7, 2007.	
	C02	Brief in Support of Defendants' Motion For Leave To Amend Answer To Assert Allegations Of Inequitable Conduct, Civil Action No. 03-0084 (E.D. Pa.), dated August 7, 2007.	
	C03	Amended Answer And Counterclaims Of Defendant, Civil Action No. 03-0084 (E.D. Pa.), dated August 7, 2007.	
	C04	BRETT R. BOLHOFNER, et al., "The Results Of Open Reduction And Internal Fixation Of Distal Femur Fractures Using a Biologic (Indirect) Reduction Technique," Journal of Orthopedic Trauma, Vol. 10, No. 6, pp. 372-377, Lippincott-Raven Publishers, Copyright 1996 (attached as Exhibit A to Amended Answer)	
	C05	USPTO Web Site Record re: Application No. 09/848,251, dated May 22, 2007, listing Paul Bianco and Brian Poissant (attached as Exhibit E to Amended Answer)	
	C06	Information Disclosure Statement bearing docket no. 8932-410, dated May 4, 2001 (attached as Exhibit F to Amended Answer)	
	C07	Information Disclosure Statement in Application No. 09/660,287, dated November 13, 2000 (attached as Exhibit G to Amended Answer)	
	C08	USPTO Web Site Record re: Application No. 09/660,287, dated May 22, 2007 (attached as Exhibit H to Amended Answer)	
	C09	C. KRETTEK et al, "LISS Less Invasive Stabilization System," AO International Dialogue, Vol. 12, Issue 1, June 1999 (attached as Exhibit I to Amended Answer)	
	C10	KENNETH J. KOVAL, et al., "Distal Femoral Fixation: A Biomechanical Comparison of the Standard Condylar Buttress Plate, A Locked Buttress Plate, And The 95 Degree Blade Plate," Journal Of Orthopedic Trauma,	

NYI-4019895v1

EXAMINER**DATE CONSIDERED**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO. 8932-807-999	APPLICATION NO. 10/665,431
	APPLICANT WEAVER et al.	
	FILING DATE September 22, 2003	ART UNIT 3733

NON PATENT LITERATURE DOCUMENTS

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		Volume 11, Issue 7, pp. 521-524, October 1997, Lippincott-Raven Publishers (attached as Exhibit J to Amended Answer)	
	C11	"Less Invasive Stabilization System (LISS) Technique Guide," Synthes (USA) Copyright 2000 (attached as Exhibit K to Amended Answer)	
	C12	Printout of http://www.aofoundation.org web site, dated May 23, 2007 (attached as Exhibit L to Amended Answer)	
	C13	C. KRETTEK, et al., "LISS: Less Invasive Stabilization System," AO Dialogue, 1999 (attached as Exhibit M to Amended Answer)	
	C14	Printout from USFDA 510(k) Premarket Notification Database, dated May 23, 2007, listing Synthes Distal Femur Plate (DFP) System, and bearing 510(k) number K982222 (attached as Exhibit N to Amended Answer)	
	C15	510(k) Summary For Synthes (USA)'s Distal Femur Plate (DFP) System (K982222), dated July 29, 1998 (attached as Exhibit O to Amended Answer)	
	C16	Printout from USFDA 510(k) Premarket Notification Database, dated May 22, 2007, listing Synthes Anatomical Locking Plate System, and bearing 510(k) number K961413 (attached as Exhibit P to Amended Answer)	
	C17	510(k) Summary For Synthes (USA)'s Anatomical Locking Plate System (K961413), dated August 7, 1996 (attached as Exhibit Q to Amended Answer)	
	C18	Printout from USFDA 510(k) Premarket Notification Database, dated May 22, 2007, listing Synthes 2.4 mm Universal Locking Plate System, and bearing 510(k) number K961421 (attached as Exhibit R to Amended Answer)	
	C19	510(k) Summary For Synthes (USA)'s 2.4 mm Universal Locking Plate System (K961421), dated June 26, 1996 (attached as Exhibit S to Amended Answer)	
	C20	Synthes' Response To Motion For Leave to Amend Answer, Civil Action No. 03-0084 (E.D. Pa.), dated August 9, 2007	

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EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	